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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EREZO, DARWIN P	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,439	WELLER ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2009*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-60 and 100-117* is/are pending in the application.

4a) Of the above claim(s) *53-60 and 100-117* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. This Office action is in response to the applicant's communication filed on 7/28/09.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,478,791 to Carter et al. in view of US 6,592,596 to Geitz.

Carter discloses a method of acquiring tissue comprising: positioning a first and second acquisition members **52** adjacent to a region of tissue, wherein the first and second acquisition members are in apposition to one another along a first longitudinal axis in an open configuration (Fig. 9A); adhering tissue with the first and second acquisition members by compressing the tissues between the first and second acquisition members in a closed configuration (Fig. 9B); fastening the tissue between the first and second acquisition members with at least one fastener **24**; removing the first and second acquisition members from the region of tissue (after surgery); reconfiguring the first and second acquisition members from a closed configuration to an open configuration prior to positioning (Fig. 9A); wherein positioning the first acquisition member and the second acquisition member comprises aligning the members adjacent to a lesser curvature (closing the acquisition members); wherein adhering tissue could be is done simultaneously by the first and second acquisition members.

Carter is silent with regards to the method of folding tissues from within a hollow body organ by advancing the first and second acquisition members transesophageally into the hollow body organ (during surgery); wherein adhering tissue comprises drawing

tissue into each of the first and second acquisition members via a vacuum force; and adhering tissue sequentially.

However, the use of a device for creating a fold from within a hollow body organ is well known in the art. For example, Geitz discloses a device that is advanced transesophageally into the stomach area (hollow body organ). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Carter to create a fold from within a hollow body organ since the use of such devices is well known in the art, as taught by Geitz, and since it has been held that use of a known technique (creating fold within a hollow body organ) to improve similar devices (fold creating devices) will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

With regards to the step of adhering tissues by drawing the tissues using a vacuum force, Carter discloses another embodiment in Fig. 13, wherein the device provides a vacuum force to acquire the tissue fold. Therefore, one of ordinary skill in the art would have found it obvious to modify the embodiment shown in Fig. 9A-9B to also have a vacuum orifice in the tissue acquiring members because it would better secure the tissues within the tissue acquiring members prior to closing said members.

With regards to the step of adhering the tissues sequentially, it is noted that such step would be a mere obvious design choice since the applicant has not disclosed that said step provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the acquiring tissues simultaneously or the

claimed acquiring the tissues sequentially because both steps perform the same function of acquiring tissues.

Response to Arguments

6. Applicant's arguments filed 7/28/09 have been fully considered but they are not persuasive.

The applicant argued that Carter fails to teach the steps of adhering and compressing tissue within the first and second acquisition members. However, the examiner pointed out in the rejection that the embodiment shown in Fig. 9 provides for the recited steps. The corresponding portion of the specification for Fig. 9 is reproduced below (col. 8, ll. 35-51):

> Referring now to FIGS. 9A-9C, a pivotal plication probe 50 includes a pair of arms 52 that pivot relative to shaft 42. Arms 52 again have roughened surfaces 36 to engage and draw the fascial surface inward. As the grasping arms close towards each other, roughened fold retainers 54 move distally relative to shaft 42, thereby urging the tissue surface to form fold 22 in the desired direction.
>
> Arms 52 define a plurality of inwardly oriented channels 56. Channels 56 provide access to the approximated tissues when the arms are adjacent to each other. Staplers 58 ride within channels 56, and can be advanced distally to deploy fasteners 24 (here again illustrated as staples) while the roughened fold retainers 54 extend within the folded tissue surfaces. Roughened retainers 54 can abrade adjacent portions of the adjacent tissue surfaces defining the fold when pivotal probe 50 is withdrawn proximally, thereby promoting the formation of adhesions.

Note that arms 52, which is being interpreted as the first and second acquisition members, includes roughened surfaces to “engage and draw fascial surface inward”. This step of engaging the tissue is being interpreted as the step of adhering tissue. It is also disclosed that the arms 52 are moved closer towards each other for forming the fold. This is interpreted as the compressing step.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Carter and Geitz discloses medical devices for forming and securing tissue folds. Therefore, one of ordinary skill in the art would find it obvious that the device of Carter can be used to secure different types of tissues, including the ones taught by Geitz.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773